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| 10/657,006 | 09/05/2003 | Christine Dingivan | 10271-116-999 | 3565 |

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| EXAMINER | |
|---|---|
| SKELDING, ZACHARY S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/657,006 | DINGIVAN ET AL. | |
| | Examiner | Art Unit | |
| | Zachary Skelding | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 August 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's Preliminary Amendment to the claims, filed August 12, 2004, is acknowledged.

   Claim 44 has been added.

   Claims 1-44 are pending.

2. It is noted that the instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

### *Restriction Requirement*

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

   I. Claims 1-32 and 44, drawn to method of treating disease with CD2 antagonists, classified in Class 424, subclass 130.1.

   II. Claims 33-43, drawn to CD2 antagonists, classified in Class 530, subclass 387.1.

4. Groups II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, CD2 antagonists can be used to purify or detect CD2.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

*Species Election*

6. This application contain claims directed to the following patentably distinct species of the claimed invention:

7. If applicant elects either **Group I or II,** applicant is **required to elect one specific CD2 antagonist**, for example, from the antagonists disclosed in the instant specification, for example at pages 40-53, such as "small organic molecules" **OR** "LFA-3TIP" **OR** "anti-CD2 antibody".

   These molecules and are patentably distinct because their structures, and/or physiochemical properties are different, and/or they do not share a common structure that is disclosed to be essential for common utility. Further, examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

   Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

   **AND**

   **If applicant elects "anti-CD2 antibody"** applicant must **further elect** a particular type of anti-CD2 antibody selected from the group consisting of:

   1. **"MEDI-507"** and **"an anti-CD2 antibody with the proviso that said antibody is NOT MEDI-507"** but it has the same properties as MEDI-507, i.e., "binds to an eptiope comprising amino acids 18, 55 or 59 of CD2" and/or "does not inhibit or interfere with the interaction between human CD2 and LFA-3" (as recited in claims 3 and 5, respectively), **OR**

   2. **"an anti-CD2 antibody with the proviso that said antibody is NOT MEDI-507"** (as in claim 2).

   These antibodies are patentably distinct because they bind different epitopes on CD2 and/or have different effects on the interaction between CD2 and LFA-3, which means, in turn, that the structures of these antibodies are different, and they do not share a common structure that is disclosed to be essential for common utility.

   Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

8. **Furthermore,** if applicant elects **Group I,** applicant is required to elect one specific species from **each** of **A-D**:

**A)** Applicant is required to elect a **"disease"** from, for example, the diseases disclosed in the present specification at pages 1-3 and claim 15, such as "lung cancer" **OR** "breast cancer" **OR** "T-cell prolymphocytic leukemia" **OR** "anaplastic large cell lymphoma".

These "disease" species are patentably distinct because they differ in etiologies and therapeutic endpoints. Furthermore, the examination of species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

**B)** Applicant is required to elect an **"administered cancer therapeutic"** (see claim 6) from, for example, those recited in the instant specification at pages 67-68, e.g., "paclitaxel" **OR** "palladium" **OR** "tamoxifen" **OR** "TRAIL agonists".

These "administered cancer therapeutic" species are patentably distinct because they differ in their structures, physicochemical properties and mode of action, and do not share a common structure that is disclosed to be essential for common utility. Furthermore, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

**C)** Applicant is required to elect a "**conjugated therapeutic agent or drug"** (see claim 7) from, for example, those recited in claim 21 and 24, "an antibody that binds to a tumour-associated antigen" **OR** "paclitaxel" **OR** from for example, the instant specification at page 53-57, such as "methotrexate" **OR** "cisplatin".

These "conjugated therapeutic agent or drug" species are patentably distinct because they differ in their structures, physicochemical properties and mode of action, and do not share a common structure that is disclosed to be essential for common utility. Furthermore, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

**D)** Applicant is required to elect a **"standard or experimental therapy for a T-cell malignancy"** (see claim 26) species from, for example, those recited in the instant

specification at page 68, 1st paragraph, such as "Campath" **OR** "Mylotarg" **OR** "Bexxar" **OR** "hematopoietic stem cell transplantation".

These "standard or experimental therapy for a T-cell malignancy" species are patentably distinct because they employ agents which differ in their structures, physicochemical properties and mode of action, and these agents do not share a common structure that is disclosed to be essential for common utility. Furthermore, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

9. **Furthermore**, if applicant elects **Group II**, applicant is **required to elect** one **specific "chemotherapeutic agent, radiation therapeutic agent, hormonal therapeutic agent or biological therapeutic agent"** (see claim 42) from among those listed in the instant specification at page 67-68, for example, "docetaxel" **OR** "external beam radiation therapy" **OR** "estrogen" **OR** "TRAIL agonists".

   These "chemotherapeutic agent, radiation therapeutic agent, hormonal therapeutic agent or biological therapeutic agent" species are patentably distinct because they differ in their structures, physicochemical properties and mode of action, and do not share a common structure that is disclosed to be essential for common utility. Furthermore, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

   Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

10. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

*Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.*

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

    In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

    Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding
Patent Examiner
June 16, 2006

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6/19/06